# Quality Agreement
## regarding extemporaneous preparations

### 1. Parties

| Party | Name | Address | Identification |
|---|---|---|---|
| GMP-manufacturer/<br>Contractor | Heel Belgium NV | Booiebos 25, 9031 Drongen, Belgium | 982 CP (24/03/2016) |
| Pharmacy/<br>Client | | | Customer nr:<br>APB nr: |

### 2. Legal context

In Belgium, the preparation and dispensing of extemporaneous preparations is strictly regulated. According to the Medicines Act and the guidelines of the Federal Agency for Medicines and Health Products (FAGG), the following principles apply:

- Magistral preparations may only be carried out by a pharmacist in his own pharmacy, or by a company with a preparation license (i.e., GMP manufacturer), exclusively on behalf of a pharmacist.
- The pharmacist remains responsible for the prescription, delivery to the patient, and traceability of the medicine.
- A written cooperation agreement is required to clearly define the responsibilities of both parties and to comply with the FAGG's requirements regarding quality assurance, traceability, and supervision.

### 3. Quality Agreement

**Article 1 – Purpose of the agreement**

- Both parties confirm their cooperation regarding extemporaneous preparations, as has been the case for many years in a spirit of trust and mutual appreciation.
- This agreement emphasizes the responsibilities between the pharmacy (client) and the GMP manufacturer (contractor) in the production and delivery of extemporaneous preparations.
- The pharmacy remains ultimately responsible at all times for the medicine delivered to the patient.

**Article 2 – Responsibilities of the GMP-manufacturer**

- Carrying out extemporaneous preparations in accordance with applicable legislation and GMP guidelines
- Timely and correct delivery to the pharmacy.
- Transparency regarding composition, labeling, and traceability

**Article 3 – Responsibilities of the pharmacy**

- Correct and complete transmission of prescriptions.
- Delivery to patients in accordance with legal provisions
- Maintenance of patient records and traceability
- Feedback in response to comments or complaints

**Article 4 – Compensation**

- The GMP manufacturer invoices the pharmacy according to the existing rates. Payment is made within 30 days of the invoice date.

**Article 5 – Data protection**

- Both parties undertake to comply with the GDPR when processing patient data.

**Article 6 – Duration and amendment**

- This agreement confirms the existing cooperation and may be amended or terminated at any time by mutual agreement.

## 4. Signatures

Done at Drongen on 24.09.2025.

| Party | Name | Function | Date and signature |
|---|---|---|---|
| GMP-manufacturer/ Contractor | Stefan Bollen | General Manager Heel Belgium nv | 24.09.2025  |
| Pharmacy/ Client | | | |

Accompanying email

Subject: Cooperation agreement for extemporaneous preparations

Dear Sir/Madam,

As you know, we have been producing extemporaneous preparations for many years, including for your pharmacy or company, always with a focus on quality, traceability, and trust.

In order to remain compliant with the guidelines followed by the **Federal Agency for Medicines and Health Products (FAGG)**, we need to formally renew our collaboration in order to meet the legal requirements and to document this.

We therefore enclose a short renewed collaboration agreement confirming our existing collaboration.

**Please complete and stamp this agreement (2 pages) with your details and return it to us for approval.**

The FAGG has asked us to submit this renewed cooperation agreement before **October 1, 2025**, and it will enable us to continue to deliver any future orders for extemporaneous preparations smoothly after October 1, 2025.

Thank you in advance for your trust.

Kind regards

Stefan Bollen
General Manager Heel Belgium NV
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9031 Drongen
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E-mail: info@heel.be