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Table 4. Risk categories and internal quality control examples

Risk category	Description	Internal quality control
Low risk	No measurable risk criteria; Herbal teas or cutaneous dosage forms with low-potency active substances; No risk to patients' health	Uniformity (visual inspection), appearance and colour, particle size distribution, pH, refractive index
Medium risk	One risk factor present, or additional tests needed according to the pharmacy's self-assessment; Cutaneous dosage forms: ointments, creams, lotions, gels with medium-potency active substances (e.g. topical steroids, Class II or III); Potential risk to patients' health	pH; density; drop volume/weight (standard drop counter); refractive index; fineness of dispersion (microscopy); particle size distribution (glass plate spread), consistency (penetrometry), dry residue, spreadability (extensometry), colloidal stability. If the critical values for these tests are not available in the literature, these values can be set by the pharmacy
High risk	Several risk factors present; Oral dosage forms, suppositories, eye drops, rinsing solutions; Significant potential risk to patients' health	All types of tests for the medium-risk medicinal products plus tests using semi-quantitative and quantitative analytical methods, such as colour and turbidity comparison, spot size estimation (thin-layer chromatography), uniformity of dosage units (weight variation)
Very high risk	All risk factors present; Parenteral dosage forms, cytostatics; Very significant potential risk to patients' health	The requirements of Paragraph 35 of the Ordinance on the Operation of Pharmacies (Apothekenbetriebsordnung, ApBetrO) must be fulfilled. The paragraph regulates parametric release based on the validation of production processes and process monitoring through monthly testing of rooms and staff for particles and microorganisms, monthly mock compounding of a medicinal product, as well as assays and sterility testing of each batch

The table is prepared by the authors based on the Resolution of the Working Group of Pharmacists of Germany (Arbeitsgemeinschaft der Pharmazieräte Deutschlands) dated 16.10.2013